

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Sep 2021

### Determining efficacy of smoke cessation program on quit Rate, immunological response and treatment outcome in new pulmonary tuberculosis patients: a clinical trial

#### Protocol summary

##### Summary

Tuberculosis (TB) is one of the main causes of death in the world, especially Asia. Much morbidity and mortality due to tuberculosis occur in developing countries which smoking it is very common in them. New research on various aspects of the relationship between smoking and tuberculosis protests has shown effect of smoking on clinical, bacteriological, treatment and recurrence of tuberculosis. Therefore, smoking is a significant risk factor for tuberculosis and tobacco control, so it is recommended to include smoke cessation intervention as a preventive intervention in tuberculosis control programs. This Randomized Clinical trial (RCT) will be conducted during 3 years at National Research Institute of Tuberculosis and Lung Disease (NRITLD) in Tehran. During the study, approximately 60 patients in each group should be studied. Thus, in total, 240 patients (60 patients in each arm) will be evaluated for this study. Patients will be randomly selected among new TB diagnosed Cases, who will be treated by DOTS regime. Smoking evaluation and cessation Counseling and will be offered to the Patients by Physician trained in Smoke Cessation. Patients will be divided randomly in to the intervention group and will receive related smoke cessation intervention. Patients will be followed for Smoke Cessation result at the end of second week, second, quarter and Sixth months. Immunologic evaluation included measurement of cytokine (IL-8) and Fogocytosis will be done at base line and at the end of fourth month. TB Treatment assessment will be done at the end of second, fourth and sixth months, base on negative sputum smear, in all of the study groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013062613783N1**

Registration date: **2013-08-31, 1392/06/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-31, 1392/06/09

##### Registrant information

###### Name

Mahshid Aryanpur

###### Name of organization / entity

National Research Institute of Tuberculosis and Lung Disease

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2610 9508

###### Email address

mahshidaryanpur@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2013-08-23, 1392/06/01

##### Expected recruitment end date

2014-08-23, 1393/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determining efficacy of smoke cessation program on quit Rate, immunological response and treatment outcome in new pulmonary tuberculosis patients: a clinical trial

**Public title**

Determining efficacy of smoke cessation on tuberculosis treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: current manufactured cigarette smokers will be diagnosed with active pulmonary TB: either sputum smear-positive or smear-negative, based on classification from WHO treatment guidelines; classify under treatment Category I (new TB cases) ; patients of both sexes, aged 18 years and above; speaking the Persian language. Exclusion criteria: having extra pulmonary TB only (involving CNS, pericardium, adrenal etc) ; they have multi-drug resistant tuberculosis at diagnosis ; they are living with or newly diagnosed with HIV/AIDS ; they are active IV drug abuser ; they are classified as Category II (relapse, treatment failure, and treatment after default) or Category III (chronic TB) ;they fulfill the eligibility criteria, but unwilling to participate in the study or unable to understand the contents of the informed consent form.

**Age**

From **18 years** old to **90 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **240**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

National Research Institute of Tuberculosis and lung disease

**Street address**

Masih Daneshvari Hospital-Daar abad- Niavaran

**City**

Tehran

**Postal code**

19569-44413

**Approval date**

2013-04-30, 1392/02/10

**Ethics committee reference number**

sbmu1.rec1392.17

**Health conditions studied****1****Description of health condition studied**

tuberculosis

**ICD-10 code**

A15

**ICD-10 code description**

Respiratory tuberculosis, bacteriologically and histologically confirmed

**Primary outcomes****1****Description**

tuberculosis treatment outcome

**Timepoint**

2,4,6 months

**Method of measurement**

sputum smear

**Secondary outcomes****1****Description**

smoke cessation

**Timepoint**

2-4-6 months

**Method of measurement**

urine cotinine test

**2****Description**

Immunologic response(phagocytes capacity uptake and IL-8 amount)

**Timepoint**

3 months

**Method of measurement**

flow cytometry

**Intervention groups****1****Description**

Intervention group (cessation consultation and pharmacotherapy ): smokers patients with pulmonary tuberculosis who are under Tb DOTS Treatment that

receive smoke cessation program consultation and pharmacotherapy . Cessation consultation consist of advice , assist and arrange .Four counseling sessions will be held during the first two weeks .patients will also receive sustain release Bupropion -150 mg- BD for nine weeks which will be free of charge for them.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention groups(Brief advice counseling): smokers patients with pulmonary tuberculosis who are under Tb DOTS Treatment that receive smoking cessation brief advice for three minute. This group will get a short brief advice; strongly and clearly advice to quit smoking, given the benefits of cessation and linking it with their current disease status by trained physician during their TB treatment in the first visit.

#### Category

Behavior

### 3

#### Description

Smoker Control Groups: smoker patients with pulmonary tuberculosis which are under Tb Treatment and age and sex of them are matched with intervention group. They do not receive any intervention.

#### Category

N/A

### 4

#### Description

Non Smoker Control Groups: Non smoker patients with pulmonary tuberculosis which are under Tb Treatment and age and sex of them are matched with intervention group. They do not receive any intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

National Research Institute of Tuberculosis and Lung Disease

##### Full name of responsible person

Mahshid Aryanpur

##### Street address

Masih Daneshvari Hospital -Daar Abad-Niavaran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Proffesor Mohammad Reza Masjedi

##### Street address

Daarabad-Niavaran\_Tehran

##### City

Tehran

#### Grant name

1238006

#### Grant code / Reference number

1238006

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

National Research Institute of Tuberculosis and Lung Disease

##### Full name of responsible person

Mahshid Aryanpur

##### Position

MD-MPH

##### Other areas of specialty/work

##### Street address

Masih Daneshvari Hospital -Daar Abad-Niavaran

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##### Email

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##### Web page address

www.tpcrc.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

National Research Institute of Tuberculosis and Lung Disease

**Full name of responsible person**

Prof. MohammadReza Masjedi

**Position**

Pulmonary Sun Speciality

**Other areas of specialty/work****Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

National Research Institute of Tuberculosis and Lung Disease

**Full name of responsible person**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*